K113654

510(k) Summary
for the
Caspian OCT Spinal System

JAN 12 2012

This 510(k) summary for the Caspian Spinal System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :

K2M, Inc.
751 Miller Drive SE
Leesburg, VA 20175
Telephone: 703-777-3155
Date Prepared: 01/11/12

Contact Person :
Nancy Giezen
Manager Regulatory Affairs

2. Tradename:	Caspian OCT Spinal System
Common Name:	Spinal Fixation System
Classification Name:	Spinal Interlaminal Fixation Orthosis (21CFR 888.3050)
Device Product Code:	KWP
Regulatory Class:	Class II

3. Predicate or legally marketed devices which are substantially equivalent:

- K2M Caspian Spinal System (K081107, K101084)
- DePuy Mountaineer (K110353)

4. Description of the device:

The Caspian Spinal System is a top-loading, multiple component, posterior (cervical-thoracic) spinal fixation system which consists of pedicle screws, rods, locking set screws, hooks, and rod connectors. Additional hooks are being added to the system.

Materials: The devices are manufactured from Ti6Al4V, Ti6Al4V Eli and Cobalt Chrome per ASTM and ISO standards.

Function: The system functions as an adjunct to fusion to provide immobilization and stabilization of spinal segments of the cervical and thoracic (T1-T3) spine.

5. Intended Use:

The Caspian OCT/miniMesa/miniDenali Spinal System is intended to provide stabilization as an adjunct to fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) when used with autograft or allograft and is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies), spondylolisthesis, spinal stenosis, fracture/dislocation, revision of previous cervical spine surgery, tumors, atlantoaxial fracture with instability, occipitocervical dislocation.

The occipital bone screws are limited to occipital fixation only.

The rod and hook components are intended for use in the cervical/upper thoracic (C1–T3) spine. The pedicle screws are limited to placement in T1-T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

The Caspian OCT/miniMesa/miniDenali Spinal System can also be linked to the Range Spinal System using the 3.5mm/5.5mm rod connectors or transitional rods.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The subject components were compared to the existing components of the K2M Caspian OCT Spinal System were determined not to represent worst case for the system for mechanical testing..

The design features and sizing of the subject devices were also compared to predicate devices including components of the K2M Caspian Spinal System and of Depuy Mountaineer and found to be substantially the same as these systems. It is manufactured from the same materials and is indicated for the same intended uses as these systems.

There are no significant differences between the subject implants and other devices currently being marketed. They are substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 12 2012

K2M, Inc.
% Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive, SE
Leesburg, Virginia 20175

Re: K113654
Trade/Device Name: Caspian OCT Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: December 9, 2011
Received: December 13, 2011

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 113654

Indications for Use

510(k) Number (if known): K113654

Device Name: Caspian OCT Spinal System

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Prescription Use X AND/OR Over-the-counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113654